EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to beta-glucans from oats and barley and maintenance of normal blood LDL-cholesterol concentrations (ID 1236, 1299), increase in satiety leading to a reduction in energy intake (ID 851, 852), reduction of post-prandial glycaemic responses (ID 821, 824), and “digestive function” (ID 850) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to beta-glucans from oats and barley and maintenance of normal blood LDL-cholesterol concentrations (ID 1236, 1299), increase in satiety leading to a reduction in energy intake (ID 851, 852), reduction of post-prandial glycaemic responses (ID 821, 824), and "digestive function" (ID 850) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to beta-glucans from oats and barley and maintenance of normal blood LDL-cholesterol concentrations, increase in satiety leading to a reduction in energy intake, reduction of post-prandial glycaemic responses, and "digestive function". The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The foods/food constituents that are the subject of the health claims are "barley grain fibre", "oat grain fibre", "oats beta-glucan", "barley beta-glucan", "barre céréalière diététique contenant de l'avoine", and "oatbran and oatbran products". From the conditions of use and references provided, the Panel assumes that the food constituent responsible for the claimed effects is beta-glucans from oats and barley. The Panel considers that beta-glucans from oats and barley are sufficiently characterised.

[1] On request from the European Commission, Question No EFSA-Q-2008-1608, EFSA-Q-2008-1611, EFSA-Q-2008-1637, EFSA-Q-2008-1638, EFSA-Q-2008-1639, EFSA-Q-2008-1974, EFSA-Q-2008-2037, adopted on 25 March 2011.

[2] Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: The members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Gut/Immune: Jean-Louis Bresson, Maria Carmen Collado, Miguel Gueimonde, Daisy Jonkers, Martinus Løvik, Bevan Moseley, Maria Saarela, Seppo Salminen, Yolanda Sanz, Stephan Strobel, Daniel Tomé and Hendrik van Loveren. The members of the Claims Sub-Working Group on Weight Management/Satiety/Glucose and Insulin Control/Physical Performance: Kees de Graaf, Joanne Harrold, Mette Hansen, Mette Kristensen, Anders Sjödin and Inge Tetens.

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Maintenance of normal blood LDL-cholesterol concentrations

The claimed effects are "fibres solubles (beta-glucane) et cholestérol sanguin" and "blood cholesterol level". The Panel assumes that the target population is the general population. In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the maintenance of normal blood LDL-cholesterol concentrations.

A claim on beta-glucans and maintenance of normal blood cholesterol concentrations has already been assessed with a favourable outcome.

Increase in satiety leading to a reduction in energy intake

The claimed effect is "increases satiety, prolongs satiety". The Panel assumes that the target population is the general population. The Panel considers that an increase in satiety leading to a reduction in energy intake, if sustained, might be a beneficial physiological effect.

None of the studies provided tested the sustainability of an effect of beta-glucans from oats or barley on appetite ratings and subsequent energy intake. Thus, no conclusions can be drawn from the studies provided for the scientific substantiation of the claim.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of beta-glucans from oats and barley and a sustained increase in satiety leading to a reduction in energy intake.

Reduction of post-prandial glycaemic responses

The claimed effect is "carbohydrate metabolism and insulin sensitivity". The Panel assumes that the target population is individuals who wish to reduce their post-prandial glycaemic responses. In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the reduction of post-prandial glycaemic responses. The Panel considers that reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionally increased) may be a beneficial physiological effect.

In weighing the evidence, the Panel took into account that intervention studies in healthy subjects consistently show an effect of oat and barley beta-glucans in decreasing post-prandial glycaemic responses without disproportionally increasing post-prandial insulinaemic responses at doses of about 4 g per 30 g of available carbohydrates in bread and pasta products when consumed alone or in the context of a meal, and that the mechanism by which beta-glucans could exert the claimed effect is well established.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the consumption of beta-glucans from oats and barley and a reduction of post-prandial glycaemic responses.

The Panel considers that in order to obtain the claimed effect, 4 g of beta-glucans from oats or barley for each 30 g of available carbohydrate should be consumed per meal. The target population is individuals who wish to reduce their post-prandial glycaemic responses.

"Digestive function"

The claimed effect is "beta-glucan improves digestive function". The Panel assumes that the target population is the general population. The Panel considers that "improving digestive function" without specification of the nutrients which are the target of the claim is not sufficiently defined.

The Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

KEY WORDS

Beta-glucans, oats, barley, fibre, blood cholesterol, satiety, glycaemic responses, digestion, health claims.

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INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006[4] submitted by Member States contains main entry claims with corresponding conditions of use and literature for similar health claims. EFSA has screened all health claims contained in the original consolidated list of Article 13 health claims which was received by EFSA in 2008 using six criteria established by the NDA Panel to identify claims for which EFSA considered sufficient information had been provided for evaluation and those for which more information or clarification was needed before evaluation could be carried out[5]. The clarifications which were received by EFSA through the screening process have been included in the consolidated list. This additional information will serve as clarification to the originally provided information. The information provided in the consolidated list for the health claims which are the subject of this opinion is tabulated in Appendix C.

ASSESSMENT

1. Characterisation of the food/constituent

The foods/food constituents that are the subject of the health claims are "barley grain fibre", "oat grain fibre", "oats beta-glucan", "barley beta-glucan", "barre céréalière diététique contenant de l'avoine", and "oatbran and oatbran products".

From the conditions of use and references provided, the Panel assumes that the food constituent responsible for the claimed effects is beta-glucans from oats and barley.

Beta-glucans are soluble cereal fibres. They are non-starch polysaccharides composed of glucose molecules in long linear glucose polymers with mixed β-(1→4) and β-(1→3) links with an approximate distribution of 30 % to 70 %. Their molecular weight varies from 50 to 2,000 kDa. Beta-glucans occur naturally in the bran of cereal grasses such as barley (~7 %), oats (~5 %), rye and wheat (1-2 %), and are measurable in foods by established methods. This opinion applies to beta-glucans naturally present in foods, and added to foods.

The mixed linkages are important for their physical properties, such as solubility and viscosity. Their viscosity is a function of the concentration of dissolved beta-glucans, and of their molecular weight (Wood et al., 2000), and further depends on differences in raw materials, processing and methods of determination.

The Panel considers that the food constituent, beta-glucans from oats and barley, which is the subject of the health claims, is sufficiently characterised.

2. Relevance of the claimed effect to human health

2.1. Maintenance of normal blood LDL-cholesterol concentrations (ID 1236, 1299)

The claimed effects are "fibres solubles (beta-glucane) et cholestérol sanguin" and "blood cholesterol level". The Panel assumes that the target population is the general population.

[4] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

[5] EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. EFSA Journal, 9(4):2135, 24 pp.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the maintenance of normal blood LDL-cholesterol concentrations.

A claim on beta-glucans and maintenance of normal blood cholesterol concentrations has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009).

2.2. Increase in satiety leading to a reduction in energy intake (ID 851, 852)

The claimed effect is "increases satiety, prolongs satiety". The Panel assumes that the target population is the general population.

Satiety is the decrease in motivation to eat after consumption of food. The effect may persist up to several hours, may reduce energy intake either at the next meal or across the day and, if sustained, may lead to a reduction in body weight.

The Panel considers that an increase in satiety leading to a reduction in energy intake, if sustained, might be a beneficial physiological effect.

2.3. Reduction of post-prandial glycaemic responses (ID 821, 824)

The claimed effect is "carbohydrate metabolism and insulin sensitivity". The Panel assumes that the target population is individuals who wish to reduce their post-prandial glycaemic responses.

In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the reduction of post-prandial glycaemic responses.

Postprandial glycaemia is interpreted as the elevation of blood glucose concentrations after consumption of a food and/or meal. This function is a normal physiological response that varies in magnitude and duration, and which may be influenced by the chemical and physical nature of the food or meal consumed, as well as by individual factors (Venn and Green, 2007). Decreasing post-prandial glycaemic responses may be beneficial to subjects with, for example, impaired glucose tolerance, as long as post-prandial insulinaemic responses are not disproportionally increased. Impaired glucose tolerance is common in the general adult population.

The Panel considers that the reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionally increased) may be a beneficial physiological effect.

2.4. "Digestive function" (ID 850)

The claimed effect is "beta-glucan improves digestive function". The Panel assumes that the target population is the general population.

Improved digestion or absorption of nutrients might be considered as beneficial physiological effects in a situation where digestion or absorption is a limiting factor for the maintenance of adequate status of the nutrient. The Panel considers that "improving digestive function" without identification of the nutrients which are the target of the claim is not sufficiently defined.

The Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

3. Scientific substantiation of the claimed effect

3.1. Increase in satiety leading to a reduction in energy intake (ID 851, 852)

The two references provided for the scientific substantiation of the claim reported on human intervention studies which assessed the effects of oat or barley products on appetite ratings (including satiety) after eating the test food on a single occasion (Berti et al., 2005; Granfeldt et al., 1994). One of the studies also reported on the effects of barley and oat product consumption (on a single occasion) on subsequent energy intake (Berti et al., 2005). The Panel notes that none of these studies tested the sustainability of an effect of beta-glucans on appetite ratings and subsequent energy intake (i.e. effects were tested on a single occasion and no information has been provided on the repeated consumption of the food constituent). The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has not been established between the consumption of beta-glucans from oats and barley and a sustained increase in satiety leading to a reduction in energy intake.

3.2. Reduction of post-prandial glycaemic responses (ID 821, 824)

The references provided for the scientific substantiation of the claim included publications on the health effects of dietary fibre in general, on the health effects of low glycaemic foods and/or diets, and on the effects of barley and/or oat products and/or beta-glucans on health outcomes unrelated to the claimed effect (e.g. blood lipids). The references also included human intervention studies which reported on measures of blood glucose in which the amount of beta-glucans consumed was not specified (Granfeldt et al., 1994; Liljeberg et al., 1992), or in which the study population was insulin-dependent or non-insulin dependent diabetic subjects on either insulin or oral hypoglycaemic medications (Braaten et al., 1994; Jenkins et al., 2002; Pick et al., 1996; Pick et al., 1998; Tappy et al., 1996). The evidence provided does not establish that results obtained in patient populations treated with anti-diabetic medications can be generalised to the target population with respect to post-prandial glycaemic responses. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

Three human intervention studies investigated the effects of barley and/or oat beta-glucans on post-prandial glycaemic and insulinaemic responses in healthy subjects using a standardised meal protocol in which whole-meal bread products (from oats, barley, and rye) were compared to white wheat bread (Juntunen et al., 2002; Liljeberg et al., 1996; Östman et al., 2006). All of these studies had a randomised cross-over design with washout periods longer than three days, and sample sizes between 9 and 20 subjects (men and women). Two out of the three studies (Liljeberg et al., 1996; Östman et al., 2006) observed a statistically significant reduction in post-prandial glycaemic and insulinaemic responses following consumption of the test meals which included beta-glucan-containing products (from oats or barley), compared to the test meals not containing beta-glucans, at doses between 4.6-14 g beta-glucans per 30 g of available carbohydrates. The study by Juntunen et al. (2002) did not show a significant effect on post-prandial glycaemic responses of rye bread containing 5.4 g beta-glucans in 50 g of available carbohydrate compared to white wheat bread, whereas post-prandial insulinaemic responses were significantly reduced.

Two human intervention studies investigated the effects of incorporating oat (Holm et al., 1992) or barley (Yokoyama et al., 1997) beta-glucans into pasta products (control pasta made with plain durum wheat flour) in 10 and 5 healthy subjects, respectively. These studies had a randomised cross-over design with washout periods longer than three days. Consumption of pasta with 12 g of beta-glucans in a 100 g available carbohydrate portion (about 3.6 g/30 g available carbohydrates) resulted in significantly lower and delayed peak glucose responses, and in lower peak insulin responses

(Yokoyama et al., 1997), whereas enrichment with oat bran (28 %) giving 6 % beta-glucans in the final product only slightly decreased post-prandial insulinaemic responses, while post-prandial glycaemic responses were unchanged compared to the control pasta (Holm et al., 1992).

Another test meal study, which investigated the effects on post-prandial blood glucose and insulin responses of oat and barley beta-glucan products in healthy subjects, used a standardised protocol in which sucrose was used as a control (Behall et al., 2005). Ten overweight women (mean age 50.1±7.7 years; BMI 30.3±2.2 kg/m^2) consumed glucose (1 g/kg body weight) and four test meals consisting of 0.33 g/kg body weight of carbohydrate from pudding (predominantly sucrose) plus 0.67 g/kg body weight of carbohydrates from oat flour, oatmeal, barley flour, or barley flakes to constitute a total of 1 g carbohydrates/kg body weight at breakfast after a 10 h fast. The content of beta-glucans in the test food grains was 4 and 15 g/100 g dry matter in the oat and barley test foods, respectively (about 1.8 and 6.5 g/30 g available carbohydrates, respectively). Blood samples were collected at fasting and every 30 min up to 180 min after the acute loads. Peak glucose and insulin concentrations after the barley test foods were significantly lower than those after the glucose or oat test foods. Post-prandial glucose responses (area under the curve) were significantly reduced after the consumption of oat and barley test foods when compared to sucrose. Post-prandial glucose responses after barley (flour and flakes) were significantly lower than the post-prandial glucose responses after oat (flour and oatmeal). Post-prandial insulinaemic responses were significantly reduced by barley test foods only (44-56 %, $p<0.005$). The content of beta-glucans in the barley test foods was almost four times higher than in the oat test foods, which could have explained the differential effects of the barley and oat test foods on post-prandial glucose and insulin responses.

The Panel notes that the studies above consistently show an effect of oat and barley beta-glucans in decreasing post-prandial glycaemic responses, without disproportionally increasing post-prandial insulinaemic responses, at doses of at least 4 g per 30 g of available carbohydrates.

The mechanism by which beta-glucans from oats or barley could exert the claimed effect is well established, and relates to the increased viscosity of the meal bolus when beta-glucans are added. When the meal bolus reaches the small intestine, a high viscosity delays the rate of absorption of nutrients, including glucose (Battilana et al., 2001; Wood et al., 2000; Wursch and Pi-Sunyer, 1997).

In weighing the evidence, the Panel took into account that intervention studies in healthy subjects consistently show an effect of oat and barley beta-glucans in decreasing post-prandial glycaemic responses, without disproportionally increasing post-prandial insulinaemic responses, at doses of about 4 g per 30 g of available carbohydrates in bread and pasta products when consumed alone or in the context of a meal, and that the mechanism by which beta-glucans could exert the claimed effect is well established.

The Panel concludes that a cause and effect relationship has been established between the consumption of beta-glucans from oats and barley and a reduction of post-prandial glycaemic responses.

4. Panel's comments on the proposed wording

4.1. Reduction of post-prandial glycaemic responses (ID 821, 824)

The Panel considers that the following wording reflects the scientific evidence: "Consumption of beta-glucans from oats or barley contributes to the reduction of the glucose rise after a meal".

5. Conditions and possible restrictions of use

5.1. Reduction of post-prandial glycaemic responses (ID 821, 824)

In order to obtain the claimed effect, 4 g of beta-glucans from oats or barley for each 30 g of available carbohydrates should be consumed per meal. The target population is individuals who wish to reduce their post-prandial glycaemic responses.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food constituent, beta-glucans from oats and barley, which is the subject of the health claims, is sufficiently characterised.

Maintenance of normal blood LDL-cholesterol concentrations (ID 1236, 1299)

- The claimed effects are "fibres solubles (beta-glucane) et cholestérol sanguin" and "blood cholesterol level". The target population is assumed to be the general population. In the context of the proposed wordings, it is assumed that the claimed effects refer to the maintenance of normal blood LDL-cholesterol concentrations.
- A claim on beta-glucans and maintenance of normal blood cholesterol concentrations has already been assessed with a favourable outcome.

Increase in satiety leading to a reduction in energy intake (ID 851, 852)

- The claimed effect is "increases satiety, prolongs satiety". The target population is assumed to be the general population. An increase in satiety leading to a reduction in energy intake, if sustained, might be a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of beta-glucans from oats and barley and a sustained increase in satiety leading to a reduction in energy intake.

Reduction of post-prandial glycaemic responses (ID 821, 824)

- The claimed effect is "carbohydrate metabolism and insulin sensitivity". The target population is assumed to be individuals who wish to reduce their post-prandial glycaemic responses. In the context of the proposed wordings, it is assumed that the claimed effect refers to the reduction of post-prandial glycaemic responses. Reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionally increased) may be a beneficial physiological effect.
- A cause and effect relationship has been established between the consumption of beta-glucans from oats and barley and a reduction of post-prandial glycaemic responses.
- The following wording reflects the scientific evidence: "Consumption of beta-glucans from oats or barley contributes to the reduction of the glucose rise after a meal".
- In order to obtain the claimed effect, 4 g of beta-glucans from oats or barley for each 30 g of available carbohydrates should be consumed per meal. The target population is individuals who wish to reduce their post-prandial glycaemic responses.

"Digestive function" (ID 850)

- The claimed effect is "beta-glucan improves digestive function". The target population is assumed to be the general population. "Improving digestive function" without an indication of the nutrients which are the target of the claim, is not sufficiently defined.

- The claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1608, EFSA-Q-2008-1611, EFSA-Q-2008-1637, EFSA-Q-2008-1638, EFSA-Q-2008-1639, EFSA-Q-2008-1974, EFSA-Q-2008-2037). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The full list of supporting references as provided to EFSA is available on: http://www.efsa.europa.eu/panels/nda/claims/article13.htm.

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APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods[6] (hereinafter "the Regulation") entered into force on 19th January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

a) the role of a nutrient or other substance in growth, development and the functions of the body; or

b) psychological and behavioural functions; or

c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

(i) based on generally accepted scientific evidence; and

(ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD[7]

Foods are commonly involved in many different functions[8] of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

[6] OJ L12, 18/01/2007
[7] The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.
[8] The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

(a) the claimed effect of the food is beneficial for human health,

(b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),

(c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,

(d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

WORDING OF HEALTH CLAIMS

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to

describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

TERMS OF REFERENCE

HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.

- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.

- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed.
- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

APPENDIX B

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

APPENDIX C

Table 1. Main entry health claims related to beta-glucans from oats and barley, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
821	Barley grain fibre	Carbohydrate metabolism and insulin sensitivity Clarification provided Helps to balance blood glucose/insulin. Helps to maintain normal blood glucose/insulin levels.	Stabilises sugar metabolism.
	Conditions of use - Bakery products which contain beta-glucan of barley grain fibre ≥3g/daily serving. Amount: 6g/100g of oat grain fibre. Processing of the product may weaken the utilisation of beta-glucan in the body and its health impacts. Content, viscosity, solubility and molecular weight of beta-glucan in the products should be specified to be able to refer to the utilisation of the beta-glucan present in the product. - Crushed and whole barley grits with 12g/100g of fibre, 6g/serving and low glycemic index < 55. Coarse particles slow down absorption.		
	Comments from Member States Health relationship defined		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
824	Oat grain fibre	Carbohydrate metabolism and insulin sensitivity. Clarification provided Helps to balance blood glucose/insulin. Helps to maintain normal blood glucose/insulin levels.	Stabilises sugar metabolism.
	Conditions of use - Bakery products with ≥3g/100g of beta-glucan of oat grain fibre. Amount: 6g/100g of oat grain fibre. Processing of the product may weaken the utilisation of beta-glucan in the body and its health impacts. Content, viscosity, solubility and molecular weight of beta-glucan in the products should be specified to be able to refer to the utilisation of the beta-glucan present in the product. - Dark, fibre-rich pasta with 6-11g/100g of oat, rye and wheat fibre, 4-7g/serving and glycemic index <55. Preparation process of pasta changes starch into more slowly absorbing form and the compact structure slows down absorption. Other substances consumed at the same meal influence the glycemic index.		

	Comments from Member States Health relationship defined		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
850	Oats beta-glucan	Beta-glucan improves digestive function.	Kaera kiudaine beeta-glükaani tarbimine soodustab seedimist. Kaera kiudaine beeta-glükaani tarbimine aitab soodustada seedimist. Clarification provided Consuming beta-glucan promotes digestion, improves digestive function.
	Conditions of use - Tootja poolt esitatud andmete põhjal on beeta-glükaani päevane soovitatav kogus 3 g, märgistuselt peaks ilmnema, kui suure koguse sellest toode annab.		
	Comments from Member States Consuming beta-glucan promotes digestion, improves digestive function.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
851	Oats beta-glucan	Beta-glucan increases satiety, prolongs satiety.	Kaera kiudaine beeta-glükaani tarbimine suurendab küllastustunnet ehk täiskõhutunnet.Kaera kiudaine beeta-glükaani tarbimine pikendab küllastustunde ehk täiskõhutunde säilimist. Clarification provided Consuming oats beta-glucan increases satiety. Consuming oats beta-glucan prolongs the feeling of satiety.
	Conditions of use - Tootja poolt esitatud andmete põhjal on beeta-glükaani päevane soovitatav kogus 3 g, märgistuselt peaks ilmnema, kui suure koguse sellest toode annab.		
	Comments from Member States Consuming oats beta-glucan increases satiety. Consuming oats beta-glucan prolongs the feeling of satiety.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
852	Barley beta-glucan	Beta-glucan increases satiety, prolongs satiety.	Odra kiudaine beeta-glükaani tarbimine suurendab küllastustunnet ehk täiskõhutunnet. Odra kiudaine beeta-glükaani tarbimine pikendab küllastustunde ehk täiskõhutunde säilimist. Clarification provided Consuming barley beta-glucan increases satiety. Consuming oats

			beta-glucan prolongs the feeling of satiety.
	Conditions of use - Tootja poolt esitatud andmete põhjal on beeta-glükaani päevane soovitatav kogus 3 g, märgistuselt peaks ilmnema, kui suure koguse sellest toode annab.		
	Comments from Member States Consuming barley beta-glucan increases satiety. Consuming oats beta-glucan prolongs the feeling of satiety.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1236	Barre céréalière diététique contenant de l'avoine	Fibres solubles (Beta-glucane) et cholestérol sanguin.	
	Conditions of use - 750 mg de beta-glucane par portion soit au moins 1 portion par jour.		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1299	Oatbran and oatbran products	Blood cholesterol level.	Oat bran or oat products containing bran may help to maintain normal blood cholesterol level.
	Conditions of use - Minimum 100 g/day.		

GLOSSARY AND ABBREVIATIONS

BMI Body mass index